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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/872,698 06/01/01 ELSBERRY

D P-3226.04

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QM12/1003

EXAMINER
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STEPHEN W. BAUER  
MEDTRONIC, INC.  
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MINNEAPOLIS MN 55432-5604

THISSELL, I	
ART UNIT	PAPER NUMBER

3763  
DATE MAILED:

*4*  
10/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/872,698

Applicant(s)

ELSBERRY, DENNIS D.

Examiner

Jeremy T. Thissell

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 44,45 and 47-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 44,45 and 47-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a) because they fail to show element 11 which is said to be the ventricle as described in the specification. Also, element 18 is described as the hippocampus, but it looks more like a component of the inserted instrument. The examiner requests that applicant review element 18 and check that it is accurately depicting the hippocampus. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 47-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Frisch (US 4,100,246).

Frisch teaches all the claimed subject matter including the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer

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tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length (see col. 5, lines 3-45).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson et al (US 5,462,523) in view of Frisch.

Samson teaches a drug delivery catheter having a non-porous outer sleeve, and a porous inner sleeve that protrudes beyond the distal end of the outer sleeve so as to allow for perfusion of drugs through the pores. However, Samson does not teach that the outer and inner sleeve are adjustable relative to one another. Frisch teaches the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length. It would have been obvious to make the device of Samson adjustable to provide a variable surface area of porous tube for drugs to be introduced through, since it is well within the level of ordinary skill in the art to make a device adjustable.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims ~~47-58~~ <sup>should be 57 (58 cancelled)</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,093,180. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same core subject matter, that is the method of adjusting outer and inner tubes of a tubular medical device by either heating or exposing the outer tube to a solvent so as to expand it and allow the inner tube to be selectively adjusted for length.

Claims 44 and 45 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,093,180 in view of Rogers et al ("Clinical Trial of Indomethacin in Alzheimer's Disease").

Elsberry (6,093,180) teaches all the claimed subject matter except for the specifics of injecting any particular drug (Indomethacin as claimed).

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Rogers et al teach that it is known to administer indomethacin in order to treat Alzheimer's Disease. However, in the study conducted by Rogers et al, the drug was administered orally. The examiner takes the position that since it is well known to administer drugs directly in the ventricles (as taught by Elsberry) and since it is well known to treat alzheimer's disease (a brain disorder) with indomethacin, it would be obvious to one of ordinary skill in the art to inject the indomethacin of Rogers directly into the ventricles using the procedure of Elsberry.

***Possible Allowable Subject Matter***

If applicant were to file a proper terminal disclaimer for US 6,093,180), claims 44 and 45 would be allowable over the prior art of record.

The prior art does not teach or fairly suggest the combination of the claimed catheter assembly/adjustment and the use in the hippocampus or lateral ventricle to administer doses of indomethacin. As discussed in the parent case, the introduction of indomethacin to the ventricle is known [see rejections using Corrales (US Pat No 3,941,119) in view of Rogers et al ("Clinical Trial of Indomethacin in Alzheimer's Disease")]. However, there is no motivation to assemble the device used by Corrales in the manner claimed in claims 44/45, i.e. coaxial tubes wherein the outer tube is expanded when exposed to a factor (e.g. heat or solvent) so that the inner tube can be adjusted telescopically with respect to the outer tube so as to provide a desired length.

**Contacts**

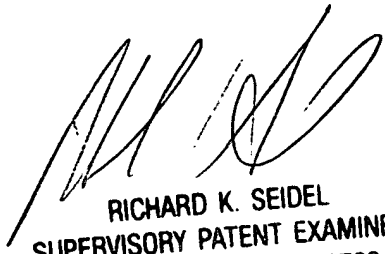
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard K. Seidel can be reached on (703) 308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-3590 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt

September 27, 2001

  
RICHARD K. SEIDEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700